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Pesticide Assessment Guidelines
Subdivision R Pesticide Spray Drift Evaluation

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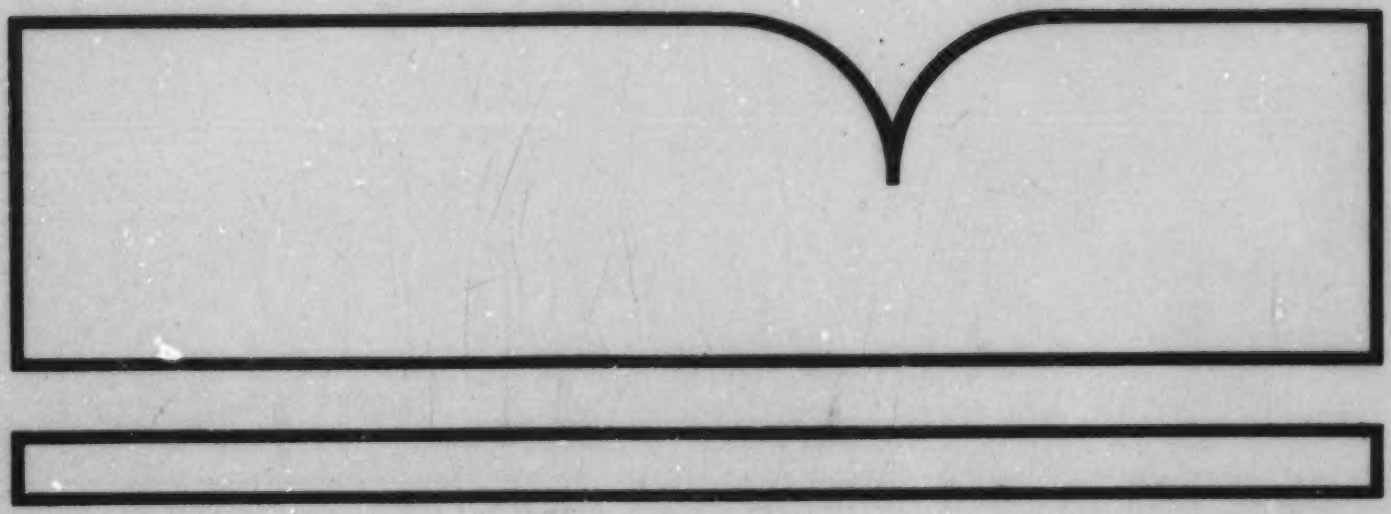

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION R

PESTICIDE SPRAY DRIFT EVALUATION

by

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Subdivison R, a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) guideline, prescribes spray drift evaluation protocols that the U.S. Environmental Protection Agency recommends to support the registration of formulated end-use products. This subdivision establishes procedures for testing and data submission concerning the evaluation of pesticide spray drift. The studies outlined by this subdivision will not be required for every product but only for selected chemicals based on their toxicity and use pattern. A summary of the rulemaking spray drift evaluation test requirements can be found in 40 CFR 158. The results of the spray drift studies together with the toxicity evaluation of the chemical to humans and nontarget animals and plants are used to assess the potential hazard of pesticides to these nontarget organisms.

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Foreword

Subdivision R describes study protocols and reporting requirements which may be used to perform pesticide aerial spray drift testing to support registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Public comment on subdivision R was accepted in a series of public meetings in October 1982 and February 1983 and papers presented at those times. Data requirements established by 40 CFR Part 158 are discussed in subdivision R so that it can be read as a complete package and so that the protocols can be explained in their proper context.

Subdivision R - Pesticide Aerial Drift Evaluation

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SUBDIVISION R -- PESTICIDE AERIAL DRIFT EVALUATION

DISCUSSION

I. Introduction

The performance requirements and testing and reporting procedures of pesticide chemical, environmental, and toxicity properties to support the registration of each pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are provided in two document series. The first is Volume 40 Part 158 of the Code of Federal Regulations (CFR) which specifies the kind of data and information that must be submitted. Section 158.142 specifies the performance requirements for pesticide aerial drift evaluation. The Agency intends to promulgate 40 CFR Part 158 as a final rule during 1984.

The second series of documents [Guideline Subdivisions, such as the present one, published by the National Technical Information Service (NTIS)] provide the test criteria and reporting procedures for the various studies. This subdivision, entitled Subdivision R - Pesticide Aerial Drift Evaluation, provides detailed information relating to the pesticide aerial drift data requirements listed in 40 CFR part 158, § 158.142. Subdivision R describes the conditions under which the aerial drift data requirements are applicable, the standards and protocols for acceptable testing, stated with as much specificity as the current scientific disciplines allow, and reporting procedures. Also provided in this subdivision are circumstances under which an applicant should consult with the Agency before initiating a study.

The pesticide spray drift protocols and reporting procedures are provided to the registrants and general public for information purposes. Results of the phytotoxicity studies found in this Subdivision will be reported to the Agency on a limited basis.

The aerial drift data submitted along with data on toxicity for humans, fish and wildlife, or plants are used to assess the potential hazard of pesticides to these organisms.

A purpose common to all tests is to provide data which will be used to determine the need for (and support the wording for) precautionary labeling or other statements to minimize the potential adverse effects to nontarget organisms. Generally, the registrant will provide adequate precautionary labeling with respect to nontarget organisms, that is, humans, domestic animals, fish and wildlife, and plants. However, there may be situations where the Agency will have to develop additional precautionary labeling.

II. ORGANIZATION

Subdivision R addresses the data requirements for the submission of pesticide aerial or spray drift data. It is organized into three section series. The first series, § 200, provides general information concerning the guidelines and relationships to other subdivisions. It also addresses submission of other data which can be substituted for the test data of droplet spectra and field evaluation of spray drift. The second series, § 201, specifies the data requirements with respect to droplet spectrum determination for the various types of nozzles and associated equipment. The third section series, § 202, provides guidance and reporting requirements for conduct of field studies using spray equipment.

Each individual test section contains an opening paragraph indicating under what circumstances and for what products the data are required. These test sections also contain specific standards and reporting requirements. In addition to these specific test standards and test requirements, the general test standards and reporting requirements apply to the conduct of the required studies.

The requirement to produce data from these studies depends on the results of toxicity studies in the other subdivisions on hazard evaluation of pesticides to nontarget organisms (Subdivisions E, F, J, and L). Due to the complexity of the criteria to progress from those effect studies to this exposure study, specific criteria cannot be readily determined and provided with this subdivision. The decision to require and perform spray drift studies will be made onn a case-by-case basis by registrant and Agency scientists. A general basis for performing these studies would be if the pesticide is toxic to nontarget organisms and the application methodology includes situations where the product may be carried off-target by air currents.

The data generated by the spray drift studies described in these guidelines are used by the Agency, along with other data, to assess the potential risk posed by use of a pesticide product, as part of making the determination as to whether EPA should register the product. This subdivision establishes standards and requirements for testing and data submissions concerning the exposure to pesticides by nontarget organisms. This exposure can be through both dermal (or foliar) and inhalation means.

No set of results from these tests will automatically preclude the registration of a pesticide product. In certain cases, limitations, precautions and/or restrictions would be imposed upon the use of the pesticide because of its ability to drift, thereby increasing its exposure potential.

The data requirements for this subdivision are a portion of the information required for an overall environmental risk assessment.

The combination of the information submitted in response to the requirements of this subdivision, with information derived from other studies performed concerning the environmental fate of the pesticide, and the effect of the pesticide on humans and domestic animals, fish, wildlife, and invertebrate animals, and nontarget plants will lead to an all-encompassing risk assessment.

III. MAJOR ISSUES

The Agency received comments from 7 persons or groups regarding the spray drift tests as found in the proposed Subpart J 1980 guidelines. The Agency also received other comments in response to public presentations made at the American Society for Testing and Materials (ASTM) symposiums on pesticide application methodology in October 1980, Philadelphia PA, and October 1982, Fort Mitchell KY, and at the Weed Science Society of America meeting in February 1983, St. Louis MO. In many cases the commenters provided information on the applicability and the scientific merit of the various tests. In response to these public comments, the Agency has modified or clarified all sections and many paragraphs of these guidelines. Only the more significant and controversial issues submitted by the public are addressed in this discussion. Many recommendations were adopted by the Agency which do not warrant discussion here.

A. General

Drift of pesticide sprays is known to affect not only nontarget plants but also nontarget animals and humans. Because of this broad spectrum of potential adverse effects from spray drift, the Agency removed the data requirements for this testing from the proposed Subpart J guidelines. These data requirements were of such nature as to warrent a new subdivision for the assessment of spray drift. This subdivision is an attempt to consolidate and standardize the test protocols and reporting procedures. They are not general restrictive regulations to be imposed where only local conditions warrent specific regulations.

With its removal from proposed Subpart J, the conduct of the spray drift tests will be based on the effects of the particular pesticides on humans and domestic animals, fish and wildlife, nontarget plants, and beneficial insects. These effects will be determined from data submitted in accordance with the requirements of Subdivisions F, E, J, and L, respectively. Accordingly the Plant Activity tests which were part of the proposed section series (proposed § 163.126-2) have been deleted. Specific end point criteria to progress from the various nontarget organism effects tests to this series of tests on spray drift will not be addressed due to the complex nature of such criteria. A general rule, though, would be that, where there is a suspected adverse effect to nontarget organisms through aerial transport of the pesticide spray, the

drift studies would be required.

One commenter stated that the Agency is attempting to conduct basic research through regulatory test requirements. The Agency feels that there has been sufficient basic research to set up meaningful data requirements on spray drift. On the matter of requiring too much data or data that would be meaningless, the Agency feels that the data available do not adequately address specific information or inherent problems that are associated with the various pesticide categories. Some categories are wettable powders, emulsifiable concentrates, flowable liquids, and oil bases. It should also be noted that when sufficient and meaningful data become available, the Agency foresees a reduction in the requirement of this data.

B. State Regulation

Several commenters expressed a concern that through requiring data on spray drift, the Agency will in effect regulate pesticide application equipment. The Agency is not attempting to regulate pesticide application equipment with respect to spray drift. The data produced by these testing requirements are used in an overall hazard assessment for each pesticide. Spray drift data are specifically used in the exposure analysis of, not only plants, but increasingly more so of wildlife and humans. This assessment may then be used for general cautions and restrictions or may be passed to the States for specific regulations or control at the local level as proposed by the State Federal Issues Research and Evaluation Group (SFIREG).

C. Test Substance

The formulated end-use product to be registered was proposed as the substance to be tested. Several commenters stated that this would lead to excessive and, therefore, expensive testing. Originally, the proposal to test each product was based on the fact that each product is unique in its physical properties, ie., surface tension, density, visco-elasticity, etc. All of these properties affect the droplet spectrum. however, this effect is minimal when compared to the effect of the selection, operation, and adjustment of the application equipment and the environmental factors through which the droplets must pass to their targets. It was noted that pesticides within categories of pesticides, ie., wettable powders, emulsifiable concentrates, flowable liquids, and oil bases, do tend to have similar physical characteristics. The categories are sufficiently discernable to allow testing of the product in question or a similar product within that category (see above) and use pattern, ie., herbicide, fungicide, insecticide, etc. If the Agency determineds that the physical properties of the pesticide in question and the respective category differ significantly, the specific formulated end-use product will be tested.

D. Droplet Spectrum Studies

In answer to comments received that requiring the droplet spectrum studies is excessive, the spectrum studies are performed to determine the influence of a number of equipment and formulation parameters. The major parameters, such as formulation, type of nozzle, and orientation to the wind shear, must be tested, both individually and collectively, in order to correctly evaluate droplet spectrum. Droplet distributions are essential information in the use of models to more accurately predict drift.

E. Field Protocols

Commenters have noted that single applications (passes) to one swath as implied by the protocols of § 202-1(b)(5)(i) would be hardly a realistic use pattern. The protocol has been changed in order to obtain a better understanding of the deposition. Multiple passes, usually three or more, of a single swath are preferred in order to obtain more statistically consistant data of the deposit or drift. Full field applications, that is, successive swaths upwind, can also be evaluated with data taken from instruments placed immediately downwind of the field.

Several commenters stated that use of an open field or runway area is more desirable because the pesticide would cause less harm if any to the target area crop. The Agency requires the use of fields where crops or other plants exist rather than the use of open fields with bare soil or over airport runways. The plants act as dampening devices and have a strong effect on the extent of the swath displacement and other airborne movement of the pesticide. If non-crop fields with plants of similar height and density are available, their use is recommended.

Commenters from several interested groups noted that the studies included the testing of various ground equipment. This was also stated to be excessive testing. It was pointed out that boom, hydraulic, ground sprayers used by farmers, and other applicators are used very close to the crop or ground ie., one to two feet, and there is virtually no wind sheer across the nozzle. Upon reviewing these facts, the Agency agrees that this type of testing is not necessary for registration and has deleted the requirement to test hydraulic boom, ground spray equipment. Voluntary testing of ground rigs is still encouraged in order that the applicators become familiar with any possible drift from their equipment.

Applications through overhead sprinklers or irrigation equipment where the liquid is sprayed up into the air still pose a problem similar to mist blowers. Therefore, overhead sprinkler or irrigation equipment applications must still be tested.

Rights-of-way applications using "cannon" nozzles can also lead to problems of off-target exposure. However, this is generally

an applicator rather than a pesticide, equipment, or weather problem. Accordingly, data reports on this type of equipment are not required.

F. Collection Devices

Several commenters noted that some of the collection devices were excessive in number or that their placement was inordinant. The number of collection devices for the field evaluations as stated in the proposed guidelines was quite flexible. What is required is sufficient data to "present a definitive uninterrupted picture of deposits across the treated swath as well as outside the target area" [§ 202-1(b)(4)].

The placement of the air samplers and recorders of temperature and wind on 10 m towers can lead to some difficulties in obtaining and maintaining the towers and equipment. The minimum tower that will be required will be 3 m (10 feet). Temperature differences for the Barad stability determination will be measured at crop height and 2 meters above that. Wind direction and velocity should be measured at a 1 to 2 meter height above the canopy. For tall crops, taller towers may be needed to obtain temperature gradients at and 2 m above the top of the crop canopy.

The use of air samplers as noted by a commenter was not germane to Subdivision J plant tests. Air samplers were added because the Agency desired airborne particle exposure data not so much for plants but for humans and other animals. It should be noted that in order to gather maximum data on the extent of airborne material, ideally 3 to 4 samplers should be placed on each tower at each station. This is not a requirement but is highly desirable. Air samplers at 3 locations downwind are imperative, though.

G. Exposure Assessment

An exposure assessment is being requested as part of the report provided to the Agency [§ 202-1(d)]. The purpose of this report is for the registrant to make an evaluation as to the extent of possible exposure with respect to the quantity of pesticide to which nontarget organisms including humans may be exposed. The spray drift exposure assessment is a portion of an overall exposure assessment which may include assessments with respect to pesticides in ground and surface waters.

An overall risk assessment is also desirable in which the registrant compares the pesticide exposure with toxicity of the pesticide. From this, the degree of risk with respect to that use pattern may be determined.

SUBDIVISION R - PESTICIDE AERIAL DRIFT EVALUATION GUIDELINES

Series 200: GENERAL

§ 200-1 Overview.

(a) General. (1) Scope. This subdivision deals with the data submittal to support the registration of all outdoor use pesticides that are to be applied by aerial application methods (fixed- or rotary-wing), by air carrier (mist blowers), or by overhead sprinkler irrigation devices. This submission provides guidance to test and report the extent of exposure that occurs to nontarget organisms, ie., humans, fish and wildlife, and plants, by aerially transported pesticides. Though the extent of pesticide drift from other ground application equipment are not specifically required, there may be instances where the estimated environmental exposure would indicate a need for field testing with this equipment.

(2) Organization. (i) This subdivision contains two areas of data requirements:

(A) Droplet size spectrum studies (§ 201-1); and

(B) Field evaluation of pesticide drift (§ 202-1).

(ii) These data must be derived from tests and reported in a manner which complies with the general test standards contained in § 120-3 and the general reporting requirements contained in § 120-4 as well as the specific standards and reporting requirements of each section listed in paragraphs (a)(2)(i) and (ii) of this section.

(b) Requirements. (1) "When required" and "test substance" requirements. The registration applicant should be careful to distinguish between the "when required" and the "test substance" paragraph requirements of each section of this subdivision:

(i) The "when required" paragraphs pertain to the circumstances under which data shall be required, and specify the categories of products for which data must be generated to support registration applications. The test data are ordinarily required to support the registration of each end-use product with the prescribed use pattern and each manufacturing-use product used to make such an end-use product.

(ii) The "test substance" paragraphs refer to kinds of

testing required to produce acceptable data, and state the kind of pesticide material that must be used in each test. The test substance for studies in this subdivision will be a typical end-use formulated product. Generally, this test substance is prepared by the basic manufacturer of a pesticide chemical.

(2) Testing to meet requirements. Since studies found in this subdivision would ordinarily be conducted by the basic manufacturer, pesticide formulators would not often be expected to conduct such tests themselves to develop data to support their individual products. (See 40 CFR §158.50 concerning the formulator's exemption). They may do so if they wish, but they may also merely rely on the data already developed by the basic pesticide manufacturer.

(c) Data requirements. The drift hazard of a pesticide applied either by aircraft or ground equipment shall be determined in two stages. The initial stage involves the determination of possible detrimental effects to nontarget organisms that may be produced through dermal (or foliar) exposure to the pesticide. See Subdivisions E, F, J, and L to determine if a potential exists. The second stage (see §§ 201-1 and 202-1) is a combined study of both determination of droplet size spectrums and field evaluation. The droplet size spectrum study would indicate which of the conventionally used nozzle types, orifice sizes and cores, operating conditions, adjuvants, formulations, and discharge orientations would produce the greatest probable drift potential (for example, greatest volume of droplets less than 100 microns in diameter). The field studies involve commercial equipment to determine the extent of spray drift (concentration vs. distance) from swath and airborne displacement under "worst case" equipment and environmental (e.g., inversion) conditions. Determination of the spray droplet size spectrum may be performed by two alternative methods. It may be performed either using wind tunnels or during the field study evaluation using commercial equipment.

(d) Substitution of data. (1) The requirement to submit test data established by §§ 201-1 (Droplet size spectrum) and 202-1 (Field evaluation) may be satisified by the submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to those for the formulated product when used according to commonly recognized practices. Such submitted information must be accompanied by a statement of reasons why the registration applicant considers that the characteristics of his product are identical or similar to those of the designated formulation described in the published information.

(2) A registrant may feel that his product has superior or different characteristics regarding spray drift patterns with respect to resultant toxicity other than that which published or unpublished test data would demonstrate. If the applicant chooses not to use available information as provided by paragraph (c)(1) of this section, he may use this subdivision as guidance for

studies he may wish to conduct to support his product.

(e) Relation to other subdivision requirements. (1) The data requirements of other subdivisions are imposed such that duplicative testing is avoided to meet the requirements of 40 CFR Part 158. Where data are submitted to fulfill the requirements of one subdivision, cross references to that data should be made by the registrant if the data are also required elsewhere.

(2) The registration applicant is referred to Subdivision H "Labeling for Pesticides and Devices" for requirements on pesticide labeling. One of the important objectives of the testing programs required in Subdivision R is to develop sufficient data to support appropriate and adequate precautionary statements and instructions for use with respect to spray drift. Applicants should read the appropriate paragraphs of § 100-9 and section series 104 of Subdivision H dealing with spray drift.

§ 200-2 Definitions.

Terms used in this subdivision shall have the meanings set forth in FIFRA at § 162.3 of the FIFRA sec. 3 regulations, and at §60-2 of Subdivision D. In addition, for the purposes of this subdivision:

(a) The term "drift" as defined in 40 CFR 162.3(n) means movement of a pesticide through air during or immediately after applicaton or use to a site other than the intended site of application or use. Drift includes two major components:

(1) Swath displacement downwind: that which is deposited in or adjacent to the intended target area.

(2) Extended airborne displacement: that which is carried and deposited beyond and not necessarily adjacent to the target area.

(b) The term "nontarget organism" means any plant, animal, or human species not considered to be pests. These species are not intended to be controlled, injured, killed, or detrimentally affected in any way by a pesticide.

(c) The term "target area" means the area intentionally treated with a pesticide when label use directions are followed.

§ 200-3 Basic test standards.

(a) Scope. This section contains test standards that apply to all studies in this subdivision. If a specific test of this subdivision (R) contains a standard on the same subject, that specific test standard shall take precedence in the performance of that particular study.

(b) General. The experimental design, execution of the experiments, classification of the organism, sampling, measurement, and data analysis in support of an application for registration must be accomplished by use of sound scientific techniques recognized by the scientific community. The uniformity of procedures, materials, and reporting must be maintained throughout the toxicity evaluation process. Refinements of the procedures to increase their accuracy and effectiveness of the evaluation are encouraged. When such refinements include major modifications of any test procedure or standard, the Agency should be consulted before implementation. All references supplied with respect to protocols or other test standards are provided as recommendations.

(c) Personnel. (1) All testing and evaluation must be done under the direction of personnel who have the education, training, and/or experience to perform the testing and evaluation in accordance with sound scientific experimental procedures.

(2) To help assure consistency in the development of data, one person should be responsible for each particular phase of study.

(d) Test substance. (1) Spray drift evaluation tests to support the registration of a pesticide shall employ the formulated product(s), as specified in the following series of sections in this subdivision: 201, and 202.

(2) The composition of the test substance shall be reported, including the name and quantity of adjuvants and surfactants, in order to account for 100 percent of the test sample in accordance with § 61-1 of Subdivision D. The typical end-use product (formulated product) shall be within the limits, if any, certified in accordance with § 62-2.

(3) Field tests may use samples from several lots due to the volume and geographical requirements. The samples should be stored under conditions that maintain their purity and stability. In the case of formulated products, storage should be under conditions as found in commonly-recognized storage practices.

(e) Nontarget organism test species. Bioassays may be used to evaluate the extent of pesticide exposure as found in section series 202. For these tests:

(1) Healthy organisms must be used.

(2) Either domesticated, cultured (cultivated), or wild indigenous organisms may be used; endangered or threatened species as determined by the Endangered Species Act of 1973 (Public Law 93-205) shall not be used.

(3) Test organisms that are obtained from natural systems and which are to be used for testing should be maintained under conditions similar to their natural or normal cultural environment.

(f) Nontarget organism safety. While performing field tests, all necessary measures shall be taken to ensure that nontarget plants and animals, especially endangered or threatened species, are not adversely affected either by direct hazard or by impact on food supply or food chain.

(g) Controls. Where bioassays are used, bioassay control groups are used to assure that effects observed are associated or attributed to the test substance exposure. The appropriate control group should be similar in every respect to the test group except for exposure to the test substance. Within a given study, all test organisms including the controls should be from the same source. To prevent bias, a system of random assignment of the test organisms to test and control groups is required.

(h) Equipment. All equipment used in conducting the test, including equipment used to prepare and administer the test substance, and equipment to maintain and record environmental conditions, should be of such design and capacity that tests involving this equipment can be conducted in a reliable and scientific manner. Equipment should be inspected, cleaned, and maintained regularly, and be properly calibrated.

§ 200-4 Reporting and evaluation of data.

(a) Overview. This section establishes general reporting and evaluation requirements which apply to studies in the subdivision. Each test report submitted under this subdivision should satisfy the reporting requirements of this section, unless a specific section elsewhere in this subdivision directs otherwise.

(b) Submission. Data required by this subdivision should be submitted in a single report to the extent possible. Any data that have been furnished in response to the requirements of another subdivision and that are also required by this subdivision either shall be referenced to specific pages in other volumes or shall be duplicated and submitted in the volumes containing spray drift data.

(c) Content. The test report should include a complete and accurate description of test procedures and evaluation of the test results. It should also contain a summary of the data, an analysis of the data, sufficient data for the Agency to verify calculated statistical values, and a statement of conclusions to be drawn from the analysis. The summary should contain sufficient detail to permit the reader to understand the conclusions of the author. In addition to the specific information required by § 201-1, through § 202-1 of this subdivision, the test report should include the following information:

(1) Language. The English language shall be used in all test reports. English tranlations must be provided with foreigh language reports.

(2) General information. Each report should contain:

(i) Dates on which study began and ended;

(ii) Name and address of laboratory or institution performing the test;

(iii) Location where the test was performed;

(iv) Names of principal investigators and the name, address, and phone number of the employer;

(v) Certification by the applicant that the report is a complete and unaltered copy of the report provided by the testing facility.

(3) Test method. Each report should contain a statement regarding the test method used, including a full description of the experimental design and procedures.

(4) Test substance. The report shall identify the test substance, and shall include chemical name and percentage of active ingredient, and qualitative and quantitative description of the formulation composition.

(5) Control data. Due to the wide diversity of pesticide properties, use patterns, and organisms exposed in the field environment, specific reporting requirements for control values (as to source, sampling regime, and total number of sample data submitted) will depend upon the complexity and variability of the environment in which the test is to be conducted.

(6) Test equipment. The report should include a description of the test equipment used, and photographs or detailed descriptions of nonstandard equipment.

(7) Units of measurement. Reporting units should be in the metric system, but the English system may be used, in addition.

In no instance should the systems be mixed (e.g., kilograms/acre).

(8) Calculations and tabular and graphic information. Each report should contain the principal mathematical equations used in generating and analyzing data, as well as representative calculations using these equations. Tables and graphs may be used to illustrate the data.

(9) Location. Geographic location of the test site, including relation to the target sites, should be reported. This portion should contain a description of the aquatic or terrestrial site to which the pesticide is applied.

(10) Data evaluation. Evaluation of data submitted to fulfill the requirements of this subdivision should take into account and be used by the Agency in the assessment of the following environmental hazards:

(i) The direct consequences to humans resulting from exposure to pesticide residues remaining in the target areas after application, as a result of ingestion of contaminated rotational crops, edible fish and shellfish, contamination of drinking water, and other similar sources, and by inhalation of the airborne pesticide mists;

(ii) The indirect consequences to humans from the presence of widely distributed and persistent pesticide spray drift in the environment, possibly resulting in loss of usable land, water, and wildlife resources; and

(iii) The potential environmental exposure of domestic, cultivated, or wild nontarget organisms to pesticide spray drift that may either be taken up and accumulated in the food web or result in loss of habitat.

(d) References. Copies of references of literature used in modifying the test protocol, performing the test, making and interpreting observations, and compiling and evaluating the results should be submitted. Copies of unpublished literature should also be included. Copies of the recommended literature referenced in these guidelines are not required.

Series 201: DROPLET SIZE SPECTRUM STUDIES

§ 201-1 Droplet size spectrum studies.

(a) When required. (1) Data on the droplet size spectrum are required by 40 CFR Part 158 on a case-by-case basis to support the registration of each formulated end-use product expected to be applied by aerial, air carrier mist blower, and by overhead sprinkler irrigation application equipment. The data are required when the detrimental effect level of those nontarget organisms anticipated to be present is exceeded. [See Subdivision E, F, J, and L to determine if the pesticide detrimentally affects fish and wildlife, humans, nontarget plants, and beneficial insects, respectively.] [See § 120-1(c).]

(2) In lieu of the wind tunnel study required by this section, droplet size distribution may be determined under field conditions during the spray drift evaluation test as provided in § 202-1.

(b) Test standards. In addition to those test standards set forth in § 200-3, the following standards apply:

(1) Test substance. A formulated end-use product of the same formulation category as the end-use product to be registered, ie., wettable powders, emulsifable concentrates, etc., and use, ie., herbicide, insecticide, etc., will be tested.

(2) Equipment. The label-recommended or commonly-used nozzles and associated parts, nozzle pressures, and nozzle discharge orientation that would produce droplets that would be most conducive to spray drift should be tested.

(3) Meteorological conditions. (i) For wind tunnel studies, the following conditions should be tested:

(A) The product should be tested at various temperature levels from 10 to 35°C.

(B) The air flow (velocity) in the wind tunnel may be adjusted to relate to the type of equipment used [e.g., 130 to 225 kmph (80 to 140 mph) for fixed-winged aircraft and air carriers, 65 to 110 kmph (40 to 70 mph) for helicopter (rotary-winged aircraft), and 5 to 40 kmph (3 to 25 mph) for ground applications (including sprinkler irrigation) other than air carriers (mist blowers)].

(ii) For field determination studies, the meteorological conditions should be those most conducive to spray drift (relatively high temperature, low relative humidity, and inversion). Field studies with the elevated temperatures are conducted to determine the effect of a higher evaporation rate on the droplets.

(4) Collection devices. The collection devices should be either laser particle measuring systems, collection cards (flat horizontal or vertical surfaces), air samplers, or other devices by which droplet size distribution can be determined.

(c) Reporting. In addition to those reporting requirements set forth in § 202-1, the following data are required:

(1) The nozzle type, orifice size, and core identification;

(2) The nozzle pressure and flow rate;

(3) The nozzle discharge orientation to the airstream;

(4) Air velocity past the nozzle;

(5) Descriptions of techniques and size determination devices;

(6) Particle size distribution vs. cumulative percent volume and particle size distribution vs. droplet number (frequency) (an attempt should be made to determine the droplet size distribution where droplet formation is finalized);

(7) Product formulation, diluent and extent of dilution, mixtures, adjuvants, and their physical properties (surface tension, viscosity, density, vapor pressure, etc); and

(8) Air temperature and relative humidity (not required for wind tunnel studies where droplets near the nozzles are measured).

Series 202: DRIFT FIELD EVALUATION

§ 202-1 Drift field evalution.

(a) When required. (1) Data on the extent of potential drift of a pesticide are required by 40 CFR Part 158 on a case-by-case basis to support the registration of each formulated end-use product expected to be applied by aerial, air carrier mist blower, and by overhead irrigation sprinkler application equipment. The data are required when the detrimental effect level of those nontarget orgainisms anticipated to be present is exceeded. [See Subdivision E, F, J, and L to determine if the pesticide detrimentally affects fish and wildlife, humans, nontarget plants, and beneficial insects, respectively.] [See § 120-1(c).]

(2) Experimental use permits will usually be required for conduct of these field evaluations where field applications are made of an unregistered product.

(b) Test standards. In addition to the test standards set forth in § 200-3, the following test standards apply:

(1) Test substance. (i) A formulated end-use product of the same formulation category as the end-use product to be registered, ie., wettable powders, emulsifable concentrates, etc., and use, ie., herbicide, insecticide, etc., will be tested. Use of dyes or other indicators with the pesticide are acceptable only if these materials do not interfere with chemical analysis or bioresponse, do not alter chemical or physical properties of the diluted spray, do deposit in direct proportion to concentrations of active ingredients, and do remain stable until analysis.

(ii) Tank mixes and package mixes. Drift data requirements for each package mix, and for each tank mix allowed in labeling are identical to those requirements for any single pesticide applied alone; that is, the droplet spectrum, and swath displacement should be evaluated. Alternatively, the swath displacement data for the mixture may not be required if the mixture activity spectrum, droplet size spectrum, and physical data are sufficiently similar to such data characterizing the mixture's most phytotoxic single component for which acceptable swath displacement data have been submitted.

(2) Dosage levels. Maximum label-recommended pesticide dosages should be evaluated in all spray drift field evaluations.

(3) Study location. The site should be typical in geography, topography, season, and meteorology of those sites within intended use patterns. The use of two or more topographically and meteorologically diverse sites is recommended in order to ascertain

the effects of these variables on spray drift. The evaluation should preferably be performed in a field(s) having foliage or crop cover conditions similar to actual use conditions. Open fields (not runways) may be acceptable only for evaluation of pesticides to be applied directly to soil or just emerging plants. If it is felt that barren fields should be used to test a product where vegetation would exist according to the label recommendations, the justification should be submitted to indicate the reason for this test modification.

(4) Collection surface placement. (i) Collection surfaces for fallout sampling should be located:

(A) Within the target area, at least one swath width upwind, and at known distances outside the target area downwind to a minimum of 1000 feet for aerial and air carrier applications and 500 feet for other ground applications (including sprinkler irrigation systems);

(B) In a straight line approximately parallel to a stable wind direction and as close as possible to the perpendicular of and centered to the direction of travel for the application equipment; and

(C) At the soil surface or, if vegetation is present, at a level which corresponds to the height of the surrounding canopy.

(ii) Air samplers, such as a high volume type (20-50 ft^3/min), should be placed at a 2- to 3-meter height at at least three down wind collection stations [for example, at 200, 600, and 1000 feet (60, 80, and 300 meters) downwind] to sample airborne particles of the chemical. The filters on the air samplers should be changed frequently in order to minimize stripping of pesticide from the filter.

(iii) While lateral distances between collection stations are left to the discretion of the applicant, it is important that a sufficient number of collection stations be established to present a definitive uninterrupted picture of deposits across the treated swath as well as outside the target area. Location of collection stations is particularly critical in areas where deposition rates are expected to change rapidly over a small lateral distance.

(5) Protocols. (i) Spray drift evaluation data from one or more applications to a single swath line are acceptable. Multiple applications (passes) to a single swath are preferred. Full field applications can be made. When bioassays are used in the swath displacement test, multiple passes over the same swath may be made only if the bioassay organisms are no closer than one swath width downwind. The length of the treated swath should be such that the spray cloud, if extended, would pass over the most distant downwind collection devices, taking into account the probability that wind

direction may not coincide perfectly with the line of collection points. Normally the spray line should equal the sampling line length, that is, the spraying line should be 1000 feet in length if the downwind sampling line is 1000 feet.

(ii) At least one study should be conducted using equipment, equipment adjustment and operation, procedures, and conditions most conducive to drift as would be allowed in labeling, and as determined in part from droplet spectrum tests. As an example, evaluate the spray drift using the following parameters that would be permitted in normal application practices: maximum recommended nozzle height (from the ground), nozzle pressure, crosswind velocity, temperature gradient at the canopy and 2 meters above it, ground speed of the equipment, pesticide dosage, and airstream shear force (nozzle discharge orientation to air stream); minimum recommended nozzle orifice diameter, spray volume, and relative humidity; and using cores or any other devices to increase droplet dispersion or produce sheets, fans, or cones.

(c) Reporting. In addition to data reporting information required by § 200-4, the following information should be submitted:

(1) A diagram of the plot indicating north, swath width, and orientation, and location and spacing of the collection stations;

(2) Temperature at two levels, wind velocity and direction, variations in velocity and direction during the application, relative humidity, atmospheric pressure, and air stability. The latter is expressed as Barad's stability ratio:

$$SR = \frac{T_3 \text{ meters} - T_1 \text{ meters}}{(\text{ave. wind vel.})^2} \times 10^5$$

Temperature should be determined just above the canopy (T_1) and at least 2 meters above that (T_3) for all applications. A standard vertical separation should be 2 meters. Wind velocity should be determined at at least 1 to 2 meters above the canopy height;

(3) Dosage of active ingredients or acid equivalent per hectare (or acre). The concentration of the final diluted spray mixture (in the spray tank) should be sampled, chemically analyzed, and reported;

(4) Physical property data, including droplet size, viscosity, density, vapor pressure, visco-elasticity, and surface tension;

(5) Spray volume (liters per hectare or gallons per acre) and carrier(s). The maximum and minimum carrier volumes recommended on the label should be reported;

(6) Adjuvant identification and dilution used;

(7) The ground speed of application equipment, the number of swaths sprayed during exposure of collecting surfaces, and swath width;

(8) A description of the spray equipment, including nozzle type, orifice size or core, nozzle pressure, nozzle spacing and arrangement, and nozzle discharge orientation. Nozzle discharge orientation should be designated in degrees related to the direction of travel of the spray equipment. Zero degrees indicates a horizontal nozzle discharge pointing rearward (opposite to the equipment direction of travel), 90° indicates a vertical nozzle discharge pointing downward, and 180° indicates a horizontal nozzle discharge pointing forward (with the equipment direction of travel);

(9) The estimated minimum and maximum nozzle-to-target height.

(10) The quantity of active ingredient(s) or acid equivalent collected or detected at each sampling point in terms of kilograms per hectare (pounds per acre); and

(11) Where droplet size distribution is determined during the field evaluation, refer to § 201-1(c) for the reporting requirements.

(d) Exposure assessment. Employing the field evaluation data provided in paragraph (c) of this section, the registrant should make an exposure assessment with respect to the quantity of pesticide to which nontarget organisms including humans may be exposed. Comparison of the toxicity data from studies conducted for plants, animals, or humans to the exposure that may occur may be made as a part of an overall risk assessment for nontarget organisms and humans. The assessment should apply primarily to the nontarget areas adjacent to the intended application sites.